

20565 Adulteration and misbranding of "SM" antiseptic powder, and misbranding of Neofem, "SM's" vaginal suppositories, Neofem capsules, and Dr. R. H. Simmons' silver and mercury. U.S. v. 21 Large and 21 Small Packages of Dr. R. H. Simmons "SM" Antiseptic Powder, et al. Default decrees of condemnation, forfeiture, and destruction. (F. & D. nos. 29185 to 29189, incl. Sample nos. 342-A to 346-A, incl.)

Examination of the drug preparations involved in these cases disclosed that the articles contained no ingredients or combinations of ingredients capable of producing certain curative and therapeutic effects claimed in the labeling. The SM antiseptic powder, and SM's vaginal suppositories were represented to have antiseptic properties, whereas they were not antiseptics when used as directed.

On November 5, 1932, the United States attorney for the Northern District of California, acting upon reports by the Secretary of Agriculture, filed in the District Court of the United States for the district aforesaid libels praying seizure and condemnation of 21 large and 21 small packages of Dr. R. H. Simmons "Sm" antiseptic powder, 22 packages of Neofem, 21 packages of "Sm's" vaginal suppositories, 22 packages of Neofem capsules, and 13 packages of Dr. R. H. Simmons' silver and mercury. It was alleged in the libels that the articles had been shipped in interstate commerce on or about August 20, 1932, by S. M. Laboratories, Inc., from Seattle, Wash., that they remained in the original unbroken packages at San Francisco, Calif., that they were misbranded in violation of the Food and Drugs Act as amended, and that the "Sm" antiseptic powder was also adulterated.

Analyses of samples of these products by this Department showed that the "SM" antiseptic powder consisted essentially of boric acid and zinc sulphate, small proportions of salicylic acid and menthol, and a trace of berberine; that the Neofem consisted essentially of alcohol, glycerin, phenolphthalein, volatile oils, including apiol and savin oil, and water, flavored with licorice and colored with chlorophyll; that the "SM" vaginal suppositories consisted essentially of cocoa butter, containing small proportions of quinine sulphate and boric acid; that the Neofem capsules consisted essentially of extracts of plant drugs, including a laxative drug, and small proportions of apiol and savin oil, colored with chlorophyll; and that Dr. R. H. Simmons' silver and mercury consisted essentially of water containing colloidal silver and mercury stabilized by a protein. Bacteriological examinations showed that the "SM" vaginal suppositories were not antiseptic; and that the "SM" antiseptic powder was not antiseptic in the dilutions recommended for use.

Adulteration of the "SM" antiseptic powder was alleged for the reason that the strength and purity of the article fell below the professed standard or quality under which it was sold, namely: "Antiseptic Powder * * * dissolve 2 teaspoonfuls of 'SM' Antiseptic Powder in $\frac{1}{2}$ pint of warm water * * * dissolve a heaping teaspoonful of 'SM' Antiseptic Powder in a pint of warm water."

Misbranding of the "SM" antiseptic powder was alleged for the reason that the following statements appearing in the labeling were false and misleading: (Carton) "'SM' Antiseptic Powder has high germicidal value. It is an ideal antiseptic for personal hygiene and general home needs. To make an effective Antiseptic Solution, dissolve 2 teaspoonfuls of 'SM' Antiseptic Powder in $\frac{1}{2}$ pint of warm water. Heat to dissolve completely. Always have such a solution ready for uses as indicated below and for other purposes where a good Antiseptic Solution is wanted. As a Mouth Wash: Rinse the mouth thoroughly with the Antiseptic Solution. As a Gargle: Use the Antiseptic Solution. For Nasal Application: Use Antiseptic Solution. By means of an inhaler or atomizer, spray carefully every two or three hours. * * * 'Sm' Antiseptic Powder is the recommended Douche Powder to be used in connection with 'SM' Suppositories. To prepare the Douche, dissolve a heaping teaspoonful of 'SM' Antiseptic Powder in a pint of warm water. Use at a temperature of from 98 to 113 Fahrenheit. Use as required"; (circular) "Dr. Richard H. Simmons' 'SM' Antiseptic Powder. On opening a package of 'SM' Antiseptic Powder you notice the clean pleasing aroma, indicative of its antiseptic qualities. * * * 'SM' presents to the discerning woman the utmost in a * * * actually beneficial antiseptic powder. Having * * * germicidal value, it is the ideal scientific antiseptic for feminine hygiene and general home needs. * * * As a Douche: * * * Dissolve a heaping teaspoonful of 'SM' Antiseptic Powder in a pint of water * * * As an Effective Antiseptic Solution: Dissolve two teaspoonfuls of 'SM' Antiseptic Powder in $\frac{1}{2}$ pint of warm water. Heat to dissolve completely. Always have such a solu-

tion ready for uses as indicated below and for other purposes where a good Antiseptic Solution is wanted." Misbranding of the said "SM" antiseptic powder was alleged for the further reason that the following statements regarding the curative or therapeutic effects of the article, appearing in the circular, were false and fraudulent: "Women whose work necessitates their being on their feet all day often suffer from back-ache, leucorrhea or other enervating weaknesses. A warm douche of 'SM' Antiseptic Powder quickly relieves this uncomfortable, painful condition. Don't be a slave to that tired, listless feeling. Douche daily with 'SM' Antiseptic Powder—retain your vivacity—erase those worry and fatigue lines. Through your sense of well being you will unconsciously retain that mental serenity and confidence so necessary at all times to your personal charm and daintiness."

Misbranding of the Neofem was alleged for the reason that the following statements, appearing on the carton and bottle labels and in a circular shipped with the articles, regarding the curative and therapeutic effects of the article, were false and fraudulent: (Carton) "For Amenorrhoea and Dysmenorrhoea. * * * The contents of this package is suggested for the treatment of Amenorrhoea (unnatural absence or suppression of the menses) and Dysmenorrhoea (difficult and painful menstruation). If used regularly each month, it will assist nature in reinstating the regular periods and menstrual functions. Caution: Do not use during pregnancy as it may cause a miscarriage"; (bottle) "For Amenorrhoea and Dysmenorrhoea * * * Directions Four days before expected regular period, take one teaspoonful every four hours until four doses have been taken. After first day take same dose every three hours for three more days unless desired results are obtained sooner. If desired results are not obtained after four days treatment, discontinue until seven days"; (circular) "If you are troubled with uncertain periods or worried by delayed menstruation, Neofem will give you prompt relief if taken internally according to directions. Used regularly it will assist nature in reinstating regular periods and menstrual functions. Offered only as a treatment for Amenorrhoea (caused by severe colds or other unnatural suppression of the menses) and Dysmenorrhoea (difficult and painful menstruation). These uncertain periods, due to unnatural causes should not be confused with pregnancy, as the use of this medicine may easily cause a miscarriage. Sold in either liquid or capsule form. Price \$5.00."

Misbranding of the "SM" vaginal suppositories was alleged for the reason that the following statements appearing in the circular were false and misleading: "The amazing efficiency of 'SM's' is achieved through a unique method of compounding certain advanced germicides, widely recognized and highly endorsed by the medical profession. * * * allowing the antiseptic solution to mix with the normal body secretions. The resultant solution forms a highly antiseptic germicide * * * thus providing a continuing germicidal action which is the protective time element necessary for complete antisepsis. * * * 'SM's' vastly greater efficacy comes through the use of correct proportions of well-known germicides of the highest quality evenly distributed throughout each suppository. 'SM's' because of the inherent qualities of their composition, insure antiseptic action that is more than momentary." Misbranding of the said 'SM's' vaginal suppositories was alleged for the further reason that the following statements regarding its curative and therapeutic effects, appearing in the circular, were false and fraudulent: "'SM's' serve as a preventive of infection, and as a corrective to vaginitis, leucorrhea and other general catarrhal conditions of the mucous membrane of the vaginal tract."

Misbranding of the Neofem capsules was alleged for the reason that the following statements regarding the curative and therapeutic effects of the article, appearing in the circular shipped with the article, were false and fraudulent: "If you are troubled with uncertain periods or worried by delayed menstruation, Neofem will give you prompt relief if taken internally according to directions. Used regularly, it will assist nature in reinstating regular periods and menstrual functions. Offered only as a treatment for Amenorrhoea (caused by severe colds or other unnatural suppression of the menses) and Dysmenorrhoea (difficult and painful menstruation). These uncertain periods, due to unnatural causes, should not be confused with pregnancy, as the use of this medicine may easily cause a miscarriage. Sold in either liquid or capsule form. Price \$5.00. 'SM' Neofem Capsules Offered only as a treatment for Amenorrhoea (caused by severe colds or other unnatural suppression of the menses) and Dysmenorrhoea (difficult and painful menstruation). These

uncertain periods, due to unnatural causes should not be confused with pregnancy, as the use of this medicine may easily cause a miscarriage."

Misbranding of Dr. R. H. Simmons' silver and mercury was alleged for the reason that the following statements, appearing in a leaflet shipped with the article and on the carton, regarding its curative and therapeutic effects, were false and fraudulent: (Green leaflet, entitled "To the Public"), "Richard H. Simmons, M. D. Diseases of The Genito-Urinary Tract. To the Public: I have found in practice, and hope to benefit the entire populace with my findings, a treatment for the relief of pain, irritation, etc., culminating in purulent discharges. The treatment of purulent discharges is indeed simple if the correct preparation is administered. Beyond all doubt, I have found a preparation of exceptional merit that is so positive in results that I recommend it not only to the patient, but also to the physician. With care, the patient will obtain remarkable results by self-administration. There is no possible chance of injury to the urethra or prostate gland as caused by many preparations self-administered. By treatment in your own privacy, you alone are aware of your misfortune. * * * truly a discovery of note in Materia Medica, and as such, warrants utmost confidence. We sincerely believe that with full cooperation in following the directions carefully, you will obtain better results than through the use of any other form of treatment. * * * Directions for the Use of 'SM' Liquid. First, Urinate before using 'SM' and not for an hour after injection of 'SM.' * * * These injections are to be made three or four times daily. Not oftener. Do Not dilute 'SM.' Use full strength. Third, use in same way for a week or ten days after discharge ceases. During this period, it is advisable to gently massage while medicine is being held in canal. * * * In order to get the results you expect, you must assist nature, which you can do by observing the following instructions. * * * For the Protection of Humanity. A preponderance of the ills to which the inhabitants of this earth are heir, are the result of lack of knowledge. The old adage, 'An ounce of prevention is worth a pound of cure,' still holds good. Various 'SM' Products have been conceived to fill a very definite need. For recommended purposes, comparative clinical laboratory tests and observation cases indicate they have no equal"; (carton) "'SM' is a highly efficient germicide used for the treatment of certain diseases of the genito-urinary tract. It is non-irritating, deeply penetrating, and will not injure the delicate mucous membrane tissues with which it comes in contact."

On March 2 and March 3, 1933, no claimant having appeared for the property, judgments of condemnation and forfeiture were entered, and it was ordered by the court that the products be destroyed by the United States marshal.

R. G. TUGWELL, *Acting Secretary of Agriculture.*

20566. Misbranding of You-Tha-Gan and Andes. U.S. v. 120 Bottles of You-Tha-Gan and 216 Bottles of Andes. Default decrees of condemnation, forfeiture, and destruction. (F. & D. nos. 29009, 29010. I.S. nos. 18862-A, 18863-A.)

Examination of the drug preparations, You-Tha-Gan and Andes involved in these cases, showed that the articles contained no ingredients or combinations of ingredients capable of producing certain curative and therapeutic effects claimed in the labeling.

On or about October 25, 1932, the United States attorney for the Northern District of Texas, acting upon a report by the Secretary of Agriculture, filed in the District Court of the United States for the district aforesaid libels praying seizure and condemnation of 120 bottles of You-Tha-Gan and 216 bottles of Andes at Dallas, Tex., alleging that the articles had been shipped in interstate commerce on or about July 9, 1932, by the Vicksburg Chemical Co., from Vicksburg, Miss., to Dallas, Tex., and charging misbranding in violation of the Food and Drugs Act as amended. The articles were labeled in part: (You-Tha-Gan) "You-Tha-Gan * * * The You-Tha-Gan Co. * * * Houston, Texas"; (Andes) "Andes * * * International Products Co., Inc. * * * Lexington, Ky."

Analyses of samples of the articles by this Department showed that the You-Tha-Gan consisted essentially of sugar and water with a small proportion of hydriodic acid (0.14 gram per 100 milliliters); and that the Andes consisted essentially of a small proportion of extracts of plant drugs including a laxative drug and a bitter drug, sodium acetate (0.2 percent), sugar (1.8 percent), alcohol (6.7 percent by volume), and water (approximately 91 percent).